UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

DONNA EMLEY, DENNIS EMLEY, Plaintiffs, v. WAL-MART STORES, INC., L.N.K. INTERNATIONAL, INC., L. PERRIGO COMPANY, Defendants.	)	No. 1:17-cv-02350-SEB-TAB

ORDER DENYING DEFENDANTS' PETITION FOR CERTIFICATION OF INTERLOCUTORY APPEAL UNDER 28 U.S.C. § 1292(b)

This cause is before the Court on Defendants' Petition to Certify Order for Interlocutory Appeal[1] [Dkt. 202; Dkt. 204], filed on July 26, 2019, pursuant to 28 U.S.C. § 1292(b) and Rule of App. Proc. 5(a)(3). Defendants seek certification for interlocutory appeal of this Court's Entry on Motions for Summary Judgment [Dkt. 199] with respect to the single issue of whether Plaintiffs' state law failure-to-warn claims are preempted by federal law. For the reasons detailed in this entry, Defendants' Motion is **DENIED.**[2]

[1] Defendants L. Perrigo Company ("Perrigo") and Wal-Mart Stores, Inc. ("Wal-Mart") filed this petition on July 26, 2019. Defendant L.N.K. International, Inc. ("L.N.K.") moved to join the petition as well as its co-defendants' reply brief. [Dkt. 204, Dkt. 256]. L.N.K.'s Motions to Join are **granted.**

[2] On December 20, 2019, Plaintiffs filed a Notice of Supplemental Authority in support of its opposition to Defendants' Petition for Certification, which Defendant Perrigo sought to strike. [Dkt. 319, Dkt. 321]. Because the Court has not relied on Plaintiffs' newly submitted evidence in ruling on Defendants' petition, we **deny as moot** the Motion to Strike.

Background

The facts are largely undisputed and thus shall be reviewed only briefly here for purposes of this ruling. On June 11, 2015, and again on June 12, 2015, Plaintiff Donna Emley ingested two pills from a bottle of Equate-brand acetaminophen manufactured by Defendant Perrigo, which she had purchased from a Wal-Mart near her home in Fort Wayne, Indiana in 2013. On June 13, 2015, Ms. Emley noticed she had a mild rash that worsened overnight, and her eyes became itchy and watery. Believing she was suffering from an allergic reaction to something she had encountered during her recent travels to a farm in Kentucky, she thought Benadryl would help. Her husband, Plaintiff Dennis Emley, purchased Equate-brand Severe Allergy and Sinus Headache medicine from a Wal-Mart in Tennessee. This product, manufactured by Defendant L.N.K., also contained acetaminophen.

On June 14, 2015, after Ms. Emley's symptoms had yet to improve, she sought medical treatment at an urgent care center in Bowling Green, Kentucky. The attending physician directed Ms. Emley to the Bowling Green Medical Center where she was admitted for what turned into a five-day stay. On June 19, 2015, Ms. Emley was transferred to the Vanderbilt University Medical Center where she was diagnosed with Toxic Epidermal Necrolysis, a severe skin disorder associated with acetaminophen. She remained hospitalized for nearly a month.

Ms. Emley has brought several state law claims against Defendants. Relevant here, she has alleged that the Equate products were defective under the Indiana Products Liability Act, Ind. Code. Ann. § 34-20-1-1, because their labels did not contain an

adequate warning regarding acetaminophen's risk of severe skin reactions. Defendants moved for summary judgment and invoked the affirmative defense of "impossibility preemption," arguing that compliance with federal regulations, specifically those relating to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*, foreclosed their liability for failure to add any such warning.

On June 27, 2019, we issued an order granting in part and denying in part Defendants' motions for summary judgment ("Summary Judgment Order"). We specifically rejected Defendants' contention that federal regulations preempted Defendants' addition of an allergy warning to the labels of their acetaminophen products. Defendants now seek amendment of the Summary Judgment Order to include language, pursuant to 28 U.S.C. § 1292(b), allowing the following question to be addressed on immediate interlocutory appeal: Are Plaintiffs' failure-to-warn claims against Defendants preempted by federal law?

Analysis

District courts are empowered to certify an otherwise unappealable non-final order for immediate appellate review if the order "involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b). As the Seventh Circuit has explained, the statute contemplates that certification for interlocutory appeal is appropriate only when certain criteria are present: "there must be a question of *law*, it must be *controlling*, it must be *contestable*, and its resolution must promise to *speed up* the litigation." *Ahrenholtz v. Bd. of Trs. of Univ. of*

III., 219 F.3d 674, 675 (7th Cir. 2000) (*emphasis in original*). Additionally, the section 1292(b) petition "must be filed within a reasonable time after the order sought to be appealed." *Ahrenholtz*, 219 F.3d at 675-76 (emphasis in original). Unless all five criteria are met, the district court is not authorized to certify its order for an immediate appeal. *Id.* at 676.

The party moving for interlocutory appeal bears the heavy burden of persuading the court "that ***exceptional circumstances*** justify a departure from the basic policy of postponing appellate review until after the entry of a final judgment." *In re Bridgestone/ Firestone, Inc. Tires Prod. Liab. Litig.*, 212 F. Supp. 2d 903, 909 (S.D. Ind. 2002) (emphasis in original). Interlocutory certification is the exception, not the rule, and thus should only be granted "sparingly, and with discrimination," *Whitmore v. Symons Int'l Grp., Inc.*, No. 1:09-CV-391-RLY-TAB, 2012 WL 3308990, at *1 (S.D. Ind. Aug. 13, 2012), and should not be invoked "merely to provide a review of difficult rulings in hard cases." *Bridgestone/Firestone, Inc.* 212 F. Supp. 2d at 909. We address each of these prerequisites to certification below.

1. *Whether the Preemption Question is One of Law*

According to the Seventh Circuit's guidance, "question of law' as used in section 1292(b) refers to a question as to the meaning of a statutory or constitutional provision, regulations, or common law doctrine. *Ahrenholz*, 219 F.3d at 676. Accordingly, an interlocutory appeal is permissible only when the contested issue is "a 'pure' question of law rather than merely an issue that might be free from factual contest." *Id.* As the *Ahrenholz* Court directed, "[D]istrict judges should . . . remember that 'question of law'

means an abstract legal issue rather than an issue of whether summary judgment should be granted." *Id.*

Defendants here seek section 1292(b) certification of the question of whether federal regulations preempted their compliance with Indiana's products liability statute with specific reference to the labeling requirements. They contend that this question, which involves the interpretation of federal regulations, presents a pure question of law. We agree. As such, the issue presented is of the type that readily qualifies as abstract and wholly legal, as the Seventh Circuit has directed. *Id.* at 677 (*citing United Airlines, Inc. v. Mesa Airlines, Inc.*, 219 F. 2d. 605 (7th Cir. 2000)).

Plaintiffs disagree with this conclusion, arguing that "not all preemption questions" are purely legal, particularly if they are of a "fact intensive nature." Plaintiffs cite the "scores of exhibits" Defendants have attached to their summary judgment briefs as evidence of particular circumstances which would compel the appellate court to "hunt through the record" to conduct a fact-sensitive inquiry in order to provide appellate review of this Court's decision.

Plaintiffs' argument ignores the fact that our Summary Judgment Order did not turn on the factual circumstances underlying the issue of whether Defendants could have provided the disputed warning. Instead, our preemption ruling relied entirely on a legal interpretation of the relevant regulations, FDA guidance, and applicable case law. Utilizing this same approach, the Seventh Circuit could resolve the preemption issue here "quickly and cleanly" without reviewing any factual findings. This question presented is

thus precisely the type of abstract legal issue contemplated by section 1292(b). *In re Text Messaging Antitrust Litig*., 630 F.3d 622, 626 (7th Cir. 2010).

2. Whether the Preemption Question is Controlling and Contestable

Plaintiffs have not advanced an argument as to whether the preemption question before us is controlling. We have no difficulty concluding that a resolution of the issue presented "is quite likely to affect the further course of the litigation." *Sokaogon Gaming Enter. Corp. v. Tushie-Montgomery Assocs., Inc*., 86 F.3d 656, 659 (7th Cir. 1996). We thus concur with Defendants that the preemption question here is, indeed, controlling and shall next address whether it is contestable pursuant to section 1292(b), that is, the dominant dispute between the parties.

To resolve this issue, we begin with a brief review of our prior decision which Defendants seek to certify.

A. This Court's Rejection of Defendants' Preemption Defense on Summary Judgment

As observed at summary judgment, federal law provides several options to manufacturers for marketing drugs. Each option has its own distinct regulatory framework. Depending on the regulatory framework applicable to a specific drug, a manufacturer may be authorized to add warnings to drug labels unilaterally without FDA permission, or, conversely, may be barred from adding any such warnings. Consequently, the question of whether a manufacturer is preempted from complying with state law depends on how the drug may be marketed under its applicable regulatory framework.

For example, in *Wyeth v. Levine*, the Supreme Court held that the manufacturer of a drug being sold pursuant to an approved New Drug Application ("NDA") was not preempted by federal law from complying with duties to warn imposed by state law. 555 U.S. at 571 (holding that "absent clear evidence that the FDA would not have approved a change to [the drug's] label, [it would] not conclude that it was impossible for Wyeth to comply with both federal and state requirements.") In contrast, the Supreme Court in *PLVA Inc. v. Mensing* reached the opposite result with regard to the manufacturers of generic drugs marketed under an Abbreviated New Drug Application ("ANDA"). 564 U.S. 604 (2011) (holding that generic drugs have a "duty of sameness" to match their labels "at all times [to] the corresponding brand-name drug labels.") *PLIVA*, 564 U.S. at 618.

Acetaminophen was not approved pursuant to the NDA or ANDA processes, which were the regulatory schemes under review by the Supreme Court in *Wyeth* and *PLIVA*, respectively. Rather, it is manufactured and sold pursuant to the Over-the-Counter ("OTC") Drug Monograph Review Process. As explained in full in our Summary Judgment Order, the monograph process is an entirely separate regulatory system developed to allow marketing of particular OTC drugs generally recognized as safe and effective. A final monograph "constitutes final agency action from which appeal lies to the courts." 21 C.F.R. § 330.10(a)(11).

To date, however, no final monograph for acetaminophen has been enacted. Thus, acetaminophen is regulated by a tentative final monograph issued more than thirty years

ago.[3] This tentative final monograph does not contain any warnings relating to severe skin reactions such as the one allegedly suffered by Ms. Emley. However, the FDA has issued Communications and Guidance regarding the need for such warnings. Most relevant here, the FDA issued a document entitled "Guidance for Industry: Recommended Warning for Over-the-Counter Acetaminophen-Containing Drug Products and Labeling Statements Regarding Serious Skin Reactions" ("The Guidance") in November 2014.[4] This Guidance stated that the FDA "does not intend to object to the marketing of products containing the following warning language:"

> Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
> - Skin reddening
> - Blisters
> - Rash
>
> If a skin reaction occurs, stop use and seek medical help right away.

The Guidance also contained the following disclaimer:

> This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on the FDA or the public.

We thus recognized in our Summary Judgment Order that the preemption issue "hinge[d] on whether the Defendants had the ability to unilaterally add the warning at issue to the labels of their products prior to the issuance of the Guidance without violating federal law."

[3] Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Tentative Final Monograph," 53 Fed. Reg. 46204 (Nov. 16, 1988).
[4] The Guidance can be found at https://www.fda.gov/media/90572/download.

Defendants, relying on 21 C.F.R. § 331.1(c)(2), argued that they were legally bound to use only the "exact language" of the warnings established in the "applicable monograph," i.e., the tentative final monograph for acetaminophen, and to follow other federal regulations related to monographs. Any failure to do so would result in their products being deemed "misbranded," and subject them to FDA enforcement actions, fines, or criminal penalties. Plaintiffs rejected Defendants' regulatory interpretation, arguing that the term "applicable monograph" in section 331 was a reference to a final, not tentative monograph. Accordingly, we addressed whether this provision demands precise compliance when the monograph at issue had yet to be finalized.

After careful review of the applicable regulatory scheme, in light of the FDA's Guidance, we concluded that it does not, for the following reasons: the relevant regulations do not authorize any enforcement actions based on non-compliance until after a monograph is finalized, *see* 21 C.F.R. § 330.10(a)(9); 21 C.F.R. § 330.10(b); Defendants had failed to identify any manufacturer or distributor operating under a tentative final monograph that had ever faced regulatory consequences for deviating from the "exact language" of a tentative final monograph;[5] a tentative final monograph, by its

[5] At summary judgment, Defendants asserted that "the FDA has, in fact, taken regulatory action based upon the wording of drug warnings that it found to deviate from a tentative final monograph," citing to an FDA warning letter issued to Quadex Pharmaceuticals, LLC, in 2011 [Dkt. 86-20, Exh. 19]. We rejected this argument, finding that "the FDA's position in that letter was not that the product at issue was misbranded simply because its label was different from that proposed in the applicable tentative final monograph; rather, the FDA found that the label contained statements that were misleading." In support of the present motion, Defendants disagree with our interpretation of this letter, reasserting that the FDA has, in fact, taken such regulatory action. We again reject Defendant's contention; nothing in the letter indicates that the FDA sought to take regulatory action simply because the product's label deviated from its

very terms, has the legal status of a proposed rule and thus does not, as we have said, wield the force and effect of federal law; acetaminophen was not subject to 21 C.F.R. § 330.13(b)(2), which authorizes regulatory action against manufacturers of certain drugs that are not labeled in compliance with their corresponding tentative final monographs; and, finally, draft guidance issued by the FDA in 2011 indicated that obligations to comply with marketing requirements set out in a monograph do not attach until a final monograph becomes effective.

Citing *Wyeth*, we concluded that we lacked any "clear evidence" that Defendants would have faced adverse regulatory action by deviating from the exact language of the tentative final monograph by adding an allergy warning to the acetaminophen products. Accordingly, we held the doctrine of impossibility preemption did not shield Defendants' from liability. This is the ruling which Defendants seek to have reviewed on a preliminary basis by the Court of Appeals.

B. Contestability of the Issue

To justify an interlocutory appeal, section 1292(b) requires that there be a "substantial ground for difference of opinion" as to the correct outcome. The parties' disagreements reach this issue as well as to what this standard actually demands. They are not alone in their disagreements; the district courts in our Circuit have reached inconsistent conclusions as to what this standard entails, and the Seventh Circuit has not yet expressly addressed the matter. *Nat. Res. Def. Counsel v. Illinois Power Res.*, LLC,

tentative final monograph; the FDA issued the letter, with respect to the product's labeling, because the label conflated two forms of herpes, which rendered it misleading.

No. 1:13-CV-01181-JBM-TSH, 2016 WL 9650981, at *5 (C.D. Ill. Nov. 2, 2016) ("Courts have differed in their interpretations of contestable . . .[It] is the most difficult of the four requirements to determine."); *Van Straaten v. Shell Oil Prod. Co., LLC*, 813 F. Supp. 2d 1005, 1020 (N.D. Ill. 2011), *rev'd and remanded on other grounds*, 678 F.3d 486 (7th Cir. 2012) ("Courts have adopted different definitions of 'contestable.'").

"Ironically," wrote one of our sister courts, "there may be substantial grounds of difference of opinion regarding the standard which governs whether an issue of law is 'contestable.'" *In re Archdiocese of Milwaukee*, 496 B.R. 905, 912 (E.D. Wis. 2013), *rev'd and remanded on other grounds*; *Listecki v. Official Comm. of Unsecured Creditors*, 780 F.3d 731 (7th Cir. 2015). However, the prevailing approach adopted by district courts, including ours, is to impose a rigid standard for "contestability" which can be satisfied only in rare circumstances, such as when there is a "substantial likelihood" that the district court's order would be reversed on appeal. *See Van Straaten*, 813 F. Supp. 2d at 1021; *Novelty, Inc. v. Mountain View Mktg., Inc.*, No. 1:07-CV-01229-SEB-JMS, 2010 WL 11561280, at *7 (S.D. Ind. Jan. 29, 2010); *City of Joliet v. Mid-City Nat. Bank*, No. 05-C-6746, 2008 WL 4889038, at *2 (N.D. Ill. June 13, 2008). We share this view that an issue is not contestable merely because reasonable judicial minds could differ, nor is an issue contestable when the court is unguided by binding precedent. As we previously ruled:

> [T]he mere lack of judicial precedent on the issues does not establish substantial ground for difference of opinion. Indeed, if interlocutory appeals were permissible whenever there is merely the lack of judicial precedent, the effect would be no more than to obtain an appellate stamp of approval on the ruling(s) by the trial

> court. Instead, we examine the strength of the arguments in opposition to the challenged ruling. This analysis includes examining whether other courts have adopted conflicting positions regarding the issue of law proposed for certification.

BridgeStone/Firestone, 212 F. Supp. 2d at 910.

While Defendants' request for permission to take an interlocutory appeal outlines the basis for their disagreement with our Summary Judgment Order, it does not support a finding that there are substantial grounds for differences among judicial opinions as to the merits of these arguments.

Defendants rely on the lack of Seventh Circuit or Supreme Court precedent on the precise question before us in arguing that the issues are contestable. This does not suffice, however, since district courts, without contrary direction from the Seventh Circuit, have routinely held that a party seeking to establish the element of "contestability" must show more than the mere lack of precedent.[6] *Id. See also MetLife Inv'rs USA Ins. Co. v. Estate of Lindsey*, No. 2:16-CV-00097, 2018 WL 925252, at *2 (N.D. Ind. Feb. 15, 2018);

[6] Defendants rely on *Boim v. Quranic Literacy Inst. & Holy Land Found. For Relief And Dev.*, 291 F.3d 1000, 1001 (7th Cir. 2002) to argue that an issue is contestable if it has not been settled by controlling authority. There, the Seventh Circuit accepted an interlocutory appeal for "questions of first impression" regarding the interpretation of a federal statute. The *Boim* court did not address whether purely legal questions of first impression are always contestable. However, we do not believe that the Seventh Circuit intended to create such a *per se* rule. Indeed, later that same year, the Seventh Circuit rejected a party's plea that this Court abused its discretion in *Firestone/Bridgestone* when it denied certification of an order for interlocutory appeal. *In re Ford Motor Co., Bridgestone/Firestone N. Am. Tire, LLC*, 344 F.3d 648, 654-55 (7th Cir. 2003). The standard established by *Firestone/Bridgestone*—that the lack of judicial precedent does not render an issue contestable—has been regularly applied by district courts in this Circuit when evaluating petitions for interlocutory appeal. Defendants also cite *In re Text Messaging Antitrust Litig.* 630 F.3d 622, 626 (7th Cir. 2010). That case, however, is clearly distinguishable. There, the Seventh Circuit observed that federal litigation was in such "ferment" after pleading standards were altered by the Supreme Court's decisions in *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S. Ct. 1937, 173 L.Ed.2d 868 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 127 S. Ct. 1955, 167 L.Ed.2d 929 (2007) that an interlocutory appeal could provide necessary guidance. Here, no such "ferment" exists.

Webster v. Ctr. for Diagnostic Imaging, Inc., No. 1:16-CV-02677-JMS-DML, 2017 WL 5598286, at *3 (S.D. Ind. Nov. 21, 2017); *Patrick v. Pyod*, 2014 WL 5343284, at *1 (S.D. Ind. Oct. 20, 2014); *Anderson v. Foster*, No. 13-CV-256-JPS, 2013 WL 4523228, at *3 (E.D. Wis. Aug. 27, 2013); *Olympia Exp., Inc. v. Linee Aeree Italiane S.P.A.*, 437 F. Supp. 2d 780, 791 (N.D. Ill. 2006), *rev'd on other grounds*, 509 F.3d 347 (7th Cir. 2007); *Bzdawka v. Milwaukee Cty*., No. 04-C-0193, 2006 WL 8444975, at *1 (E.D. Wis. Apr. 6, 2006); *United States v. NL Indus., Inc*., No. 91-CV-578-JLF, 2005 WL 8173717, at *1 (S.D. Ill. July 12, 2005).

While questions left unanswered by controlling authorities may suffice in exceptional circumstances to warrant an interlocutory appeal, we are not relieved by that void from determining if such uncertainty warrants an exception to the normal, preferred course of litigation that culminates in a final appeal. Section 1292(b) requests are *not* to be granted merely to resolve difficult questions of law. *See Pugh v. Nat'l Collegiate Athletic Ass'n*, No. 1:15-CV-01747-TWP-DKL, 2016 WL 7100606, at *6 (S.D. Ind. Dec. 6, 2016); *Olympia Exp., Inc.*, 437 F. Supp. 2d at 791; *Bzdawka*, 2006 WL 8444975, at *1 (E.D. Wis. Apr. 6, 2006); *BridgeStone/Firestone*, 212 F. Supp. 2d at 910.

Regarding the strength of Defendants' arguments against our holding, we examine whether other courts have reached conclusions on the merits that are contrary to our own. *MetLife Inv'rs USA Ins. Co.*, 2018 WL 925252, at *2; *Thompson v. Burnett*, No. 1:15-CV-01712-TWP-DML, 2017 WL 6606536, at *2 (S.D. Ind. Dec. 27, 2017); *Collier v. Caraway*, No. 2:14-CV-00365-JMS-MJD, 2017 WL 2774493, at *2 (S.D. Ind. June 26, 2017); *Anderson v. Foster*, 2013 WL 4523228, at *3; *Olympia Exp., Inc.*, 437 F. Supp. 2d

at 791; *United States v. NL Indus., Inc*., 2005 WL 8173717, at *1; *BridgeStone/Firestone*, 212 F. Supp. 2d at 910. Our review discloses that they have not.

Apparently, only one case, *In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.*, 144 F. Supp. 3d 699 (E.D. Pa. 2015), addresses whether a tentative final monograph possesses the force of federal law sufficient to preempt state law. In *Tylenol*, the plaintiff alleged that the manufacturer of Tylenol (which contains acetaminophen) failed to warn users of the risk of liver damage associated with consuming acetaminophen. That court's holding, unlike ours, turned on an examination of the particular facts: the manufacturer had, in fact, changed its product's label, thus undermining the claim that it was "impossible" to do so. Although the court's discussion could likely have ended there, it noted: "Furthermore, Extra Strength Tylenol was and still is regulated by the Tentative Final Monograph (TFM) which is only a proposed rule." As explained by the FDA in a letter to the manufacturer regarding the alterations of dosage information on a label: "Under a TFM, manufacturers market products at their own risk and are able to make voluntary adjustments taking into context the information presented in the proposed TFM." Thus, the court concluded, "the onus [is] on them[.]" *Id.* at 730.

While Plaintiffs rely on these excerpts of the *Tylenol* decision to argue that the Eastern District of Pennsylvania's analysis aligns with our own, Defendants attempt to distinguish the *Tylenol* case while concurrently asserting that a close reading of that decision actually undercuts our holding. Defendants transmute the FDA's statement in its letter that voluntarily adjustments to products' labels should "tak[e] into context the

information presented in the proposed TFM" into an indication that the FDA mandates precise compliance with tentative final monographs. Thus, argue Defendants, the evidence cited by the *Tylenol* court contradicts our holding. We disagree with this approach. Nothing in the letter establishes that the FDA unequivocally mandates that manufacturers match the "exact language" of tentative final monographs, nor did the *Tylenol* court infer as much from the letter. The letter also does not undermine the conclusions we reached as did the Eastern District of Pennsylvania that the legal effect of a tentative final monograph is that simply of a proposed rule. We agree that there are some aspects of the decision in *Tylenol* that make it distinguishable from our case, but those distinctions do no undermine our case.

In any event, this single holding does not compel a decision to grant Defendants' petition for interlocutory appeal. Defendants' challenges to our regulatory interpretation holding that "applicable monograph" means "final monograph" is unpersuasive. Defendants fault us for failing to give the undefined term "applicable monograph" its plain and unambiguous meaning, per the definition of "applicable" in Black's Law Dictionary, which they argue is broad enough to encompass the tentative final monograph without disrupting the regulatory framework.[7]

We concede that questions of statutory interpretation can make an issue ripe for contestability, but certification of an appeal is not available merely because reasonable

[7] Black's Law Dictionary (11th ed. 2019) defines the term "applicable" as: "1. Capable of being applied; fit and right to be applied. 2. (Of a rule, regulation, law, etc.) affecting or relating to a particular person, group, or situation; having direct relevance."

minds might differ as to issues of statutory construction. *See Pugh v. Nat'l Collegiate Athletic Ass'n*, 2016 WL 7100606, at *6; *Bridgestone/Firestone*, 212 F. Supp. 2d at 909 (rejecting Defendants' argument that the contestability prong is satisfied whenever a "reasonable appellate judge could vote for reversal" because "for any difficult question of law, there are at least two supportable positions"). Here, Defendants' argument as to why "applicable monograph" should include "tentative monograph" does not foreclose alternate reasonable inferences to the effect that "applicable monograph" does *not* include tentative final monographs. We have held: Based on the plain language of the relevant regulations, the "exact language" requirement and the consequences for non-compliance do not attach until the effective date of the monograph, which does not exist until a monograph is finalized. This interpretation reflects reading the regulations "as a whole," not "a series of unrelated and isolated provisions." *Arreola-Castillo v. United States*, 889 F.3d 378, 386 (7th Cir. 2018). Defendants have not quarreled with this reasoning.

Our interpretation further is consistent with the obvious fact that the tentative final monograph, as a proposed rule, does not have the force and effect of federal law and consequently the power of preemption. This highlights the flaw in Defendants' legal theory. If the tentative final monograph *did* have the force and effect of a final regulation, then Defendants would not have been permitted to deviate from its "exact language" by virtue of the non-binding guidance from the FDA—which would not supersede codified federal regulations such as the "exact language" provision. This approach would effectively undermine the entire regulatory rule-making process.

Like the *Wyeth* court, we struggle to validate Defendants' fear of regulatory action when no such action, following the issuance of the tentative final monograph in 1988, has *ever* been charged against a manufacturer who, absent some independent basis, merely added a warning to a drug marketed under a tentative final monograph. *Wyeth*, 555, U.S. at 570 ("And the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept—neither Wyeth nor the United States has identified a case in which the FDA has done so."). We reject Defendants' attempts to invoke such fear that our Court's ruling will prevent the FDA from taking *any* regulatory action against manufacturers operating under tentative final monographs; as explained in our Summary Judgment Order, the FDA maintains the ability to take enforcement actions against such manufacturers if it believed labels are improper or misleading in some way.

Defendants stress the "novelty" of the issues presented here but fail to establish how novelty alone warrants a departure from the preferred course of litigation culminating in an appeal. While the relevant regulations do leave ample room for reasonable disagreement as to the meaning of the term "applicable monograph," this disagreement, unsupported by conflicting authorities, does not indicate a substantial likelihood that our Summary Judgment Order would be reversed on appeal. Accordingly, we hold that the issue of whether Plaintiffs' failure-to-warn claims are preempted by federal law is not "contestable."

CONCLUSION

Because the criteria for interlocutory appeal are conjunctive, not disjunctive, and Defendants have failed to satisfy all of those requirements, their request for immediate interlocutory appeal must be denied. *Ahrenholz,* 219 F.3d at 676. Defendants' Petition for Certification of Interlocutory Appeal [Dkt. 202] is accordingly **DENIED.**

Defendant L.N.K.'s Motions to Join [Dkt. 204, Dkt. 256] are **GRANTED.** Defendant Perrigo's Motion to Strike [Dkt. 321] is **DENIED AS MOOT.**

IT IS SO ORDERED.

Date: 1/8/2020

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

Distribution:

Richard M. Barnes
GOODELL, DEVRIES, LEECH & DANN, LLP
rmb@gdldlaw.com

Bonnie J. Beavan
GOODELL DEVRIES LEECH & DANN LLP
bjb@gdldlaw.com

Nicholas Gene Brunette
REMINGER CO. LPA (Indianapolis)
nbrunette@reminger.com

Charles Andrew Childers
CHILDERS, SCHLUETER & SMITH, LLC
achilders@cssfirm.com

Brett T. Clayton
REMINGER CO. LPA (Indianapolis)
bclayton@reminger.com

Neil Edwards
CHILDERS, SCHLUETER & SMITH, LLC
nedwards@cssfirm.com

Jeff S. Gibson
WAGNER REESE, LLP
jgibson@wagnerreese.com

Sean L. Gugerty
GOODELL DEVRIES LEECH & DANN LLP
sgugerty@gdldlaw.com

Katherine M. Haire
REMINGER CO. LPA (Indianapolis)
khaire@reminger.com

Logan C. Hughes
REMINGER CO., LPA - College Park
lhughes@reminger.com

Haley Johnston
FROST BROWN TODD LLC (Indianapolis)
hjohnston@fbtlaw.com

Jonathan Andrew Knoll
COHEN & MALAD LLP
jknoll@cohenandmalad.com

Gregory L. Laker
COHEN & MALAD LLP
glaker@cohenandmalad.com

Mary Nold Larimore
ICE MILLER LLP (Indianapolis)
larimore@icemiller.com

Kevin C. Schiferl
FROST BROWN TODD LLC (Indianapolis)

kschiferl@fbtlaw.com